DATE OUT: 29/ OCT / 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI / MP [X] EP [ ]
DP BARCODE No.: D294087 **File Symbol No.:** 74530-RR **PRODUCT NAME:** Glyphosate 97% Technical
COMPANY: Helm AG **PCC:** 417300
FOOD USE [ ] INTEGRATED FORMULATION [X]

FROM: Shyam Mathur, Team Leader
Product Chemistry Team
Technical Review Branch/RD (7505C)

TO: Jim Tompkins / Vickie Walters, PM 25
Herbicide Branch/RD(7505C)

INTRODUCTION:

The registrant, Helm Agro US, has resubmitted the application for the registration of Glyphosate 97% Technical. The previous application for registration of the Gluphosate technical (EPA File symbol No. 74530-G) was reviewed (PCR dated 9-17-02, D283790 and PCR dated 4-17-03, D287643) but was never approved for registration. This application has been withdrawn recently and has been replaced with the present submission. The applicant has informed that no changes have been made to the contents of:
1. Volume II (Product chemistry, manufacturing process and description of impurities) [MRID No. 459317-01]

2. Volume III (Analysis of Ingredients of Five batches of Technical Grade Glyphosate including identity of ingredients and statement of composition, analytical method) [MRID No. 459317-02]

3. Volume IV (Determination of N-nitroso-glyphosate and N-nitroso-iminodiacetic acid in five batches of technical glyohosate)[MRID No. 460205-0].

The registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 524-420.

The TRB has been asked to review the product chemistry data submitted and determine the similarity of the proposed product with registered product (Reg. No. 524-420).

SUMMARY OF FINDINGS:

1. The registrant has submitted the Confidential Statement of Formula for basic formulation (dated 08-18-03), for Glyphosate 97% TGAI. The nominal concentration (97.0%) of the AI agrees with the product label claim of 97.0%. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this herbicide. [MRID No. 459317-01]

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162. The registrant has provided the details of the manufacturing process. [MRID No. 459317-01]

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities)satisfy the data requirements for 40CFR§158.167. [MRID No. 459317-01]

QUALITY CONTROL INFORMATION IS NOT INCLUDED
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

5. The data were submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. [redacted] [MRID No. 459317-02]

6. The data submitted corresponding the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.180 [redacted] [MRID No. 459317-02]

7. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical properties) for the technical satisfy the data requirements of 40CFR 158.190. [MRID No. 456859-01]

8. During the 5 batch analysis, the registrant also carried out the analysis for nitrosamine in the technical Glyphosat [redacted] 01] [MRID No.. 460205-

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the Glyphosate 97% TGAI and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B satisfy the data requirements of 40CFR§158.155 to 158.190 and are acceptable.

2. The CSF for basic formulation (dated 08-18-03) is filled out correctly and completely. It is in compliance with PR Notice 91-2. The CSF for basic formulation is acceptable with comments.

Comment: The correct CAS No. for the active ingredient glyphosate is 1071-83-6

3. The proposed product was determined to be substantially similar to the registered product with Reg. 524-420 from product chemistry view point only. There is difference in the density values [0.50 g/ml (dry) for the registered product vs 1.74 g/ml for the proposed product] which may be caused by the way the material is packed during the determination of the density. The impurity profile for the two products is very similar. The level of nitrosamine in the proposed product [redacted]

830.1550. Product Identity: (MRID No. 459317-01)

Common Name: Glyphosate Technical

Chemical Name: N - (Phosphonomethyl)glycine

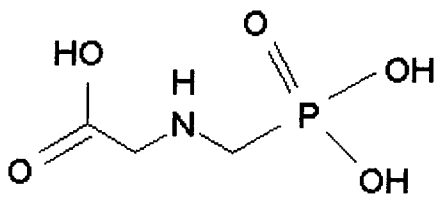
CAS No.: 1071 - 83 - 6

PC Code No.: 417300

Empirical formula: $C_3 H_8 N O_5 P$

Molecular Weight: 169.1

Structural formula:



ATTACHMENT II
REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	N - (Phosphonomethyl)glycine
Chemical Number (CAS; PC Code)	CAS No. 1071-83-6 PC Code No.: 417300
Registration/Symbol No.	74530-RR
Type of Product (T, MP, EP)	97.0% TGAI / MP
DP Barcode	D294087
Reviewer	Shyam B. Mathur
Branch Chief	Deborah McCall

Table 1: Manufacturing and Impurity Data for the Glyphosate 97% TGAI

GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product identity and composition	Basic CSF (8-18-03)	Y	The product label claim is 97.0% concurs with the nominal concentration of AI (97%) in the CSF. The UCL for the toxic impurity was provided.
830.1600	Description of materials used to produce product	459317-01	Y	The product specification sheets(MSDS) for all the starting materials have been provided
830.1620	Description of production process	459317-01	Y	The registrant has provided detailed information about the synthesis of the technical. The amounts of each starting material and conditions under which the reaction were performed are provided.
830.1670	Discussion of formation of impurities	459317-01	Y	The registrant has provided required information on the formation of impurities. The mechanisms for the formation of impurities during different stages of the production process have been submitted.
830.1700	Preliminary analysis	459317-02 460205-01	Y	Registrant has provided 5 batch analysis for the TGAI. Nitrosamine analysis was also submitted [redacted]
830.1750	Certified limits	Basic CSF (8-18-03)	Y	The certified limits for the TGAI were within the standard certified limits. The limits were verified by 5 batch analysis. The UCL for nirosoamine has been provide.
830.1800	Enforcement analytical method	459317-02	Y	[redacted]

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.
[2] Refer to CBI Appendix A for details.

QUALITY CONTROL INFORMATION IS NOT INCLUDED

Table 2: Physical and Chemical Properties of the Glyphosate 97% TGAI . *See Note for acceptance condition

GLN	Requirement	MRID	Status[1]	Result[2] or Deficiency
830.6302	Color	459317-01	Y	White
830.6303	Physical state	" "	Y	Powder
830.6304	Odor	" "	Y	No odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions		Y	Stable at normal & elevated temperature. Forms salts with Na & K. Reacts with metals like Fe, mold steel and Zn with decomposition and liberation of hydrogen gas.
830.6314	Oxidation/reduction: chemical incompatibility	" "	Y	None
830.6315	Flammability	" "	Y	Not Flammable
830.6316	Explodability	" "	Y	TS is not classified as explosive material
830.6317	Storage stability	" "	Y	Previous study indicate that TS is Stable under normal ware house conditions for at least 3 years. See Note 1
830.6319	Miscibility	NA		
830.6320	Corrosion characteristi	459317-01	Y	Glyphosate is corrosive to Fe, mild steel, Zn and Al. Glyphosate is compatible with stainless steel, glass and plastic.
830.7000	pH	" "	Y	2 . 19 (1% solution in water)
830.7050	UV/Visible absorption	" "	Y	See Note 2
830.7100	Viscosity	NA		
830.7200	Melting point/ Melting range	459317-01	Y	200° C with decomposition
830.7220	Boiling point/ Boiling range		NA	
830.7300	Density/ relative density/ bulk density	459317-01	Y	1.74 g / ml. Loose packed bulk density: 54.08 lbs / cu. ft.
830.7370	Dissociation constants in water	" "	Y	pKa = 2.6, 5.6, 10.3
830.7550	Partition coefficient (n-octanol/water), shake flask method	" "	Y	K o/w = 0.0006 - 0.0017
830.7840	Water solubility: column elution method; shake flask method	" "	Y	See Note 3 for organic solvents Water = 15,700 mg/L at pH = 7, 25° C = 11,600 mg/L at pH 2.5
830.7950	Vapor pressure	" "	Y	1.84 x 10^{-7} mm Hg at 45° C

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable ; G = Data gap
[2] For example, "brown" for 830.6302; "155° C" for 830.7200.
A* = The data are acceptable only if the registrant will provide information on the methods used to determine these properties.

BARCODE:D294087; **Reg. No.** : 74530-RR **PRODUCT**: Glyphosate 97% TGAI

Note 1. Storage stability (830.6317): [MRID No. 459317-01]

Glyphosate technical has been produced by Helm AG for many years and is known to be stable under normal warehouse storage conditions. To confirm the storage stability, 2 years study was conducted and the results are shown below:

Initial analysis: July 2, 1999		Present analysis: May 7, 2002	
Glyphosate	96.30%	Glyphosate	96.1%
Moisture	0.20%	Moisture	0.1%
Appearance	White crystals	Appearance	White crystals

After nearly 3 years storage, the glyphosate content of Glyphosate technical production batch retain sample is still 99.8% of its original analysis. It is likely the slight drop in Glyphosate analysis is due to analytical variation and not product degradation.

Note 2. 830.7050. UV / VIS: (MRID No. 459317-01)

Medium	Wavelength (nm)	Absorbance	Molar Absorption coefficient
Acidic (pH 1.93)	201 261	1.742 0.205	322.6 38.0
Neutral (pH 8.0)	201 285	0.880 0.144	160.0 26.2
Basic (pH 10.2)	201 261 281	2.640 0.207 0.155	480.0 37.6 28.2

Page _____ is not included in this copy.

Pages 7 through 13 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

✓ Identity of product impurities.

✓ Description of the product manufacturing process.

✓ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.